

Safe Chain Solutions
822 Chesapeake Drive
Cambridge, MD 21613

Title:	Standard Operating Procedures for Trading Partner Validation
Issue Date:	5/2/2015
Effective Date:	1/9/2018

PURPOSE:

To ensure Safe Chain Solutions is conducting business with authorized and properly licensed facilities and healthcare providers.

INSTRUCTIONS:

All SCS personnel will read and understand this Standard Operating Procedure so the proper steps are taken, when possible to ensure that the company operates in compliance with all applicable laws.

POLICIES:

All validations will be approved by compliance.

RESPONSIBILITIES:

<ul style="list-style-type: none"> • Compliance Team 	<ul style="list-style-type: none"> • Responsible for all trading partner validation and research
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PROCEDURES:

1. Initial Vendor Authentication and Validation

- Vendor validations will be conducted upon opening a new account with a vendor. The
- The Compliance Manager will verify all paperwork/licenses from prospective manufacturers/vendors and/or their 3PL company, if utilized. Requirements include, but are not limited to:
 - Completed agreement.
 - Confirming that the vendor has a physical place of business.
 - Copy of current wholesaler license.
 - Copy of current domicile license, if different.
 - Copy of the manufacturer/vendor current State inspection report
 - In the case of DEA Registration, current DEA Registration.
 - In the case of VAWD accreditation, current VAWD accreditation certificate.
 - Verification of compliance with licensure reporting requirements to the FDA (under DQSA section 503(e) for wholesale distributors and under section 584(b) for 3PL companies).

2. Initial Customer Authentication and Validation

- New customer validations will be conducted at the time of first sale. The customer will submit a license to their sales representative who will be responsible for notifying compliance. Compliance will then inspect license and verify active good standing with the appropriate licensing agency.
- Sales Representative will additional supply to Compliance:
 - Completed agreement(s)
 - Copy of resident state License

GOVERNMENT EXHIBIT

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- Copy of VAWD accreditation (if applicable)
- Copy of state inspection report
- Photographs of the pharmacy including behind the counter, counter area, OTC section, gift section, and outside photos.

3. General Trading Partner Requirements

- At no time will product be accepted if there is a Provider on the Transaction History.
- Potential trading partners may be denied for the following reasons: disciplinary actions against pharmacy license, shipping address does not match license address, anti-diversion methods are deemed inadequate.
- Trading partners will be asked to provide information to verify they are compliant with section 582 of the DSCSA as deemed appropriate.

4. On-Going Trading Partner Requirements

- After initial approval, all customer and vendor licenses will be reviewed at the end of each month. Any license that is close to expiration must be resubmitted with a valid expiration date before any future orders are fulfilled. Once a new license has been received, the same validation process will be applied.
- All entities must be “authorized” per Title II of the Drug Quality Security Act, as follows:
 - in the case of a manufacturer or repackager, having a valid registration in accordance with section 510 by searching
<http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>
 - in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6) by searching
<http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>
 - in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7) by searching
<http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>